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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KHARE, DEVESH	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,148	BRANTL, VICTOR	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *26-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/25/2003*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *5/13/2004* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121:

I. Claims 43-63 drawn to a pharmaceutical compositions comprising at least one ribofuranose derivative of the Formula (I), classified in classes 536, 549 and 424, subclass various.

II. Claims 26-42, drawn to a process of making the composition of Group I, classified in classes 536 and 424, subclass various.

III. Claims 1-25, drawn to a method of treatment of an inflammatory bowel disease in a subject with the ribofuranose derivative of Group I, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups **I to II** are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claims are drawn to the process of making the composition of Group I, indicating that the product can be prepared by a materially different method.

Groups **I to III** are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for making the product as claimed can be practiced with another materially different

process or (2) the product as claimed can be made in a materially different process of making that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with another materially different product i.e. a method of treating an inflammatory bowel disease in a subject can be practiced with another materially different product.

Inventions **II to III**, are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).Group II is drawn to a process of making the composition of Group I, which is unrelated to the method of treating an inflammatory bowel disease in a subject with the composition of Group I, of Group III.

Although the inventions are classified in the same class and sub-class, searching the three groups of inventions constitutes a burdensome search, as a thorough search comprises a search or foreign patents and non-patent literature as well as the appropriate U.S. patent classifications. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper. It is noted that examination of the three independent and distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

(MPEP § 821.04)

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in

the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

A telephone call was made to Wei-Ning Yang on 3/10/04 to request an oral election to the above restriction requirement. During telephone conversation with Wei-Ning Yang on 05/13/04, a provisional election was made with traverse to prosecute the invention of Group III, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-25 are currently pending in this application.

35 U.S.C. 112, first paragraph rejection

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of an inflammatory bowel disease in a subject does not reasonably provide enablement for prophylaxis or prevention of an inflammatory bowel disease in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, to determine the pharmaceutically effective amount of one or more ribofuranose derivatives having the Formula (I) applicant intends to utilize a method for prophylaxis or prevention of an inflammatory bowel disease in a subject, would require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be provided using one or more ribofuranose derivatives. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation. The quantity of experimentation needed to determine the pharmaceutically effective amount of one or more ribofuranose derivatives having the Formula (I) needed to practice the instant methods as they relate to treatment of an inflammatory bowel disease in a subject and preventing reoccurrence of the condition treated or when a healthy person is administered the active agent or multiple agents and the prevention of conditions cited supra, would require a great deal

of experimentation which would impose an undue burden upon the skilled artisan in this field. Additionally a time table for administration to achieve efficacious correlative therapy would be unduly burdensome to obtain in view of the guidance currently provided, although applicant alleges that their invention is enabled for the experimentation to administer a therapeutically effective amount of one or more ribofuranose derivatives having the Formula (I), the instant disclosure appears to be limited to the administration of one or more ribofuranose derivatives having the Formula (I) in methods for treatment of an inflammatory bowel disease in a subject.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of a pharmaceutically effective amount of one or more ribofuranose derivatives having the Formula (I) applicant intends to utilize a method for prophylaxis or prevention of an inflammatory bowel disease in a subject. There is not seen guidance as to how the skilled artisan can establish a sufficient time table or establish a prophylaxis or prevention regiment in healthy animals in the methods of the instant disclosure. There has not been provided a clear reference to prior art disclosures which give guidance as to how the skilled artisans in this art would prophylaxis or prevent an inflammatory bowel disease in a subject.

3. WORKING EXAMPLES IN SPECIFICATION

Examples 1-3, are drawn to the assay and administration of a formulation comprising a pharmaceutically effective amount of ribavirin.

The EXAMPLE advanced in the instant specification is not seen to support the breadth of the claims for prophylaxis or prevention of an inflammatory bowel disease in a subject.

4. NATURE OF THE INVENTION

It is known in this art that the composition comprising agonists of the adenosine 2a receptor can be used for the treatment of inflammatory diseases (U.S. Patents 6,610,665 and 6,518,253, see abstract and claims).

5. STATE OF THE PRIOR ART

The following patents are cited to show the state of the prior art obvious over the methods of treating inflammatory bowel disease using the composition comprising rifabutin or clarithromycin:

U.S. Patent 6,277,836.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from a composition comprising a pharmaceutically effective amount of one or more ribofuranose derivatives for prophylaxis or prevention of an inflammatory bowel disease in a subject is not seen to be disclosed in the prior art. Neither the specification nor the prior art provides adequate guidance for prophylaxis or prevention of an inflammatory bowel disease in a subject. To extrapolate the scant data and guidance provided to prophylaxis or prevention therapy would be to ignore the high degree of unpredictability in prophylaxis or prevention treatments and therapies.

7. BREATH OF THE CLAIMS

Claims 1-25 are drawn to a method of treatment or prophylaxis of an inflammatory bowel disease in a subject by administering a pharmaceutically effective amount of one or more ribofuranose derivatives. Additional claim limitations include various derivatives of ribofuranose; the ribofuranose derivatives in combination with an antiviral; and modes of administration.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to a method for prophylaxis or prevention of an inflammatory bowel disease in a subject by administering a pharmaceutically effective amount of one or more ribofuranose derivatives having the Formula (I), is that of a Ph.D. or M.D. level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims which encompass a method for prophylaxis or prevention of an inflammatory bowel disease in a subject by administering a pharmaceutically effective amount of one or more ribofuranose derivatives having the Formula (I). It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of a pharmaceutically effective amount of one or more ribofuranose derivatives, which encompass prophylaxis or prevention of an inflammatory bowel disease in a subject, would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-10 of U.S. Patent No. 6,573,248 ('248) in view of claims 1-12 of U.S. Patent 6,455,508 ('508).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '248 patent claims a method in claims 3-10 comprising administration of a set of compounds wherein said compounds are encompassed by or has substantial overlap with the compounds of the instant method. The method is drawn of treating a patient having an autoimmune disease. It is noted that autoimmune disease is disclosed to include bowel disease (col. 10, line 17). However, the instant method is a method for prophylaxis or prevention of an inflammatory bowel disease in a subject, which is the underlying mechanism of treating a patient having an autoimmune disease. It is noted the instant invention is interpreted here to mean a method for "treatment for an inflammatory bowel disease in a subject ....". It would be obvious to select any of the compounds set forth in the claims of the issued patent and administer them for the claimed method. The instantly claimed method of administering one or more ribofuranose derivatives to a subject differs from the method of '248 patent by further comprising combination with an antiviral agent such as acyclovir (claim 12) and an active agent such as interleukin II (claim 14).

The '508 patent discloses the examples of other drugs or active ingredients which can be used in combination with ribofuranose in the treatment of an autoimmune disease (abstract and claims 1-12). The '508 patent the anti-viral agents and various active agents, which can be used in combination with ribofuranose (Formula 2) (col.7, lines 40-64).

The examiner notes the instant claims and the '248 claims in view of the disclosure of the '508 patent do indeed substantially overlap and this obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571) 272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
June 4, 2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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